SUMMARY

Inspection of this manufacturer of class II medical devices was conducted as a routine FY11 work plan assignment (FACTS # 1249426). This was a level II QSIT inspection conducted per CP 7382.845 and FDA's Guide to Inspection of Quality Systems. The previous FDA inspection of this site was conducted in June 2008, and was classified NAI.

The current inspection revealed that Medrad Saxonburg, Inc continues to manufacture the higher volume disposables for Medrad's injector products. Syringe and kit manufacturing operations are highly automated, and includes pre-sterile packaging. Additional lines have been added since the previous inspection. Additionally, a third party e-beam sterilization facility has been constructed adjacent to the inspected site (b) (4)

The current inspection was one of three nearly concurrent inspections of Medrad facilities in the Pittsburgh area, each of which shares a common quality system. The EIR for the firm's Indianola location (where design cognizance resides) serves as the lead EIR for this series of inspections. Inspection of this, the firm's sterile disposables manufacturing site, focused on process controls associated with local processing activities, including in-process and finished goods inspections, incoming acceptance activities, and process and equipment qualification / validation activities. No significant objectionable conditions were observed.

ADMINISTRATIVE DATA

Inspected firm:	MEDRAD Saxonburg, Inc.
Location:	150 Victory Rd Saxonburg, PA 16056-9772
Phone:	724-360-7602
FAX:	412-406-0665
Mailing address:	150 Victory Rd Saxonburg, PA 16056-9772
Dates of inspection:	1/13/2011, 1/14/2011
Days in the facility:	2
Participants:	James M. O'Donnell, Investigator

This inspection was pre-announced by telephone. This inspection was one of a series three inspections covering local Medrad producing facilities, each of which share the common Medrad quality management system. Coincident inspection of multiple local sites impacted the reporting schedule. The inspection report for the Indianola site serves as the lead EIR for overall assessment of the Medrad quality management system.

HISTORY

Commercial production began at this site in January 2008. Additional lines have been brought on since the previous inspection of June 2008. Additionally, product has been transitioned to e-beam sterilization methodologies, and a 3rd party contract sterilizer (b) (4) has been built and commissioned adjacent to the inspected site, including a shared physical corridor connection.

INTERSTATE COMMERCE / JURISDICTION

Medrad Saxonburg manufactures syringes and packages them for subsequent sterilization alone or with other disposables as kits. Product produced is for the Medrad Stellant (CT) line. Product produced here is distributed globally. Additional detail regarding jurisdiction and interstate commerce is provided in the lead EIR for the Indianola site.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Rafael Lopez-Cepero, Plant Manager, is reportedly responsible for the daily operations of the sterile disposable manufacturing facility. Mr. Julio Rivera, Sr. VP Corporate Compliance and Management Representative received the FDA 482 Notice of Inspection Mr. Antonio Calaf, Director, SD Ops Quality, was present throughout this inspection and provided much of the information obtained. Ms. Julia Mitchell and Mr. Larry Kopyta were also present throughout this inspection.

MANUFACTURING/DESIGN OPERATIONS

The Saxonburg facility runs (b) (4) high volume automated lines engaged in syringe assembly and pre-sterile packaging of syringes and other disposables (e.g. –administrations sets, tubing, etc) into kits. Design cognizance resides at Medrad's Indianola facility. Assembly and packaging is performed in a controlled clean room environment.

COMPLAINTS / RECALL PROCEDURES

Complaints and recall procedures were reviewed as part of the inspection of Medrad's Indianola facility, and are documented in that EIR.

INSPECTION COVERAGE / FINDINGS

Inspection coverage for this facility focused on CAPA and Production and Process Control issues unique to this site. I reviewed procedures for managing non-conforming material and

reviewed examples of same. I reviewed the site's practices relating to trending and analysis of non-conforming materials (in-process, incoming and finished goods), as well as their handling and disposition of same through MRB mechanisms, including those relating to defective packaging. I reviewed Verification and Validation activities associated with Medrad's (b) (4) program, a significant effort transitioning disposable sterilization (b) (4) (b) (4) I reviewed equipment qualification activities for (b) (4) packaging integrity test system. I reviewed examples of batch device history records. I reviewed Medrad's investigation of and reactions to disposable nonconformity and complaint issues, such as some associated with bent syringe dowel pins. I reviewed incoming acceptance activities and rationales for their selected inspection plans and criteria.

No significant objectionable conditions or practices were observed for the Medrad Saxonburg facility.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

None.

GENERAL DISCUSSION WITH MANAGEMENT

Final discussions with management were relatively brief given the absence of significant adverse findings. We discussed issues associated with a failure to document a non-conformance in a batch record that arose in a single, isolated case that did not result in release of non-conforming product. Mr. Rivera, Mr. Lopez-Cepero and Mr. Calaf were present at closeout.

ATTACHMENTS

1) FDA 482, Notice of Inspection

James M. O'Donnell, Investigator